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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/675,650	09/29/2000	Ursula Busse	1619.0080001/SRL/TBB	1706

26111 7590 10/27/2004

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WASHINGTON, DC 20005

EXAMINER
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YU, MISOOK

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/675,650

Applicant(s)

BUSSE ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-12, and 24-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6, 9 and 26 is/are allowed.
- 6) ☒ Claim(s) 1-3, 10-12, 25, 27-34 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Applicant's amendments filed on 08/10/2004, and 08/24/2004 are acknowledged. As requested by applicant's representative, the amendment filed on 08/24/04 is replaced by the earlier amendment filed on 08/10/04. Claims 1-3, 5, 25-27, and 31 are amended. Claims 1-6, 9-12, and 24-34 are pending and under consideration. This Office action contains new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Specification, Withdrawn***

The objection of the disclosure due to an embedded hyperlink and/or other form of browser-executable code at page 25 line 27 is withdrawn in view of the amendment.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 3, and 25-30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in view of the amendment.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 10-12, 25, and 27-34 **remain rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to genus of isolated nucleic acid or a recombinant nucleic acid molecules comprising an additional sequence between exon 3, and 4a, resulting in a longer than SEQ ID NO:2, and to genus of cell, or non-human organism containing said recombinant nucleic molecules, or nucleic acid molecules hybridizing to 27 to 254 nucleotide of SEQ ID NO:1 or its full complement.

Applicant argues that claims meet the written description requirement because “the isolated nucleic acids molecules contains additional sequence between exon 3 and exon 4a” describes the structure of the claimed nucleic acid and “the additional nucleic acid sequence indicates that the isolated nucleic acid molecules is a differentially expressed prostate cancer antigen 3 (PCA3) mRNA indicative of anon-malignant state of the prostate” describes the relation between its structure and its function.

The argument has been fully considered but found not persuasive because claims 1, 2, 10-12, 25 do not describe the structure of the claimed “additional sequence”. Further the limitation “wherein said longer isolated nucleic acid is indicative of a non-malignant state of the prostate” does not make very much sense. The claims do not describe whether the claimed nucleic acid is under-expressed or over-expressed. One of skill in the art would not envision the structure of “additional sequence” between exon3 and 4a of PCA3, and how it is related to a non-malignant state of the prostate. A nucleic acid and non-malignant state of the prostate are two different entities. One cannot be indicative of the other.

The claims describe the structure of SEQ ID NO:2, exon 3, and exon 4a but does not describe the structure of "additional sequence" that appears to be critical for being non-malignant state. As for claims 3, and 27, and their dependent claims, the claims do not say what kinds of function is associated with the genus of hybridizing nucleic acid molecules. It is noted that law requires that the disclosure of an application shall inform those skilled in the art how to make the alleged discovery, not how to screen it for themselves.

As discussed previously Office action, and above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acid molecules, given that the specification has only described SEQ ID NO: 1, or encoding SEQ ID NO:3. Therefore, only SEQ ID NO:1, and nucleic acid encoding SEQ ID NO:3, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph.

***Claim Rejections - 35 USC § 102, Withdrawn***

The rejection of the claims under 35 U.S.C. 102(b) as being anticipated by Bussemakers et al (AT2 of IDS filed on 11/12/2003, 1993, Urol. Res. 21:452, Abstract No.P42, Springer International) as evidenced by Bussenmakers et al (Cancer Res. 1999 Dec 1;59(23):5975-9) and Figs. 3 of the instant specification is withdrawn because the art only describes nucleic acid differentially expressed but does not teach any nucleic acid being indicative of a non-malignant state of the prostate.

***The Following Are New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said longer isolated nucleic acids" in 5. There is insufficient antecedent basis for this limitation in the claim.

***Allowable Subject Matter***

Claims 6, 9, 26 are allowed because claim 6 is interpreted as drawn to a primer consisting of 10 to 50 consecutive nucleotides of nucleotide 27 to 254 of SEQ ID NO:1 and claim 9 is interpreted as drawn to kit comprising said primer inside a container.

Claims 4, and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

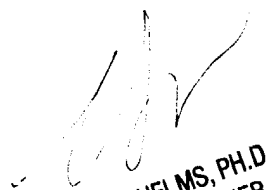
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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
LARRY R. HELMS, PH.D.  
PRIMARY EXAMINER

MISOOK YU, Ph.D.  
Examiner  
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